Health Guidance:

DHSS Interim Recommendations for PPE Sterilization, Re-use and Extended Use

April 10, 2020

This document will be updated as new information becomes available. The current version can always be viewed at http://www.health.mo.gov.

The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

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Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

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Health Guidance
April 10, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **DHSS Interim Recommendations for PPE Sterilization, Re-use and Extended Use**

Disposable filtering facepiece respirators (FFRs) decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. Each health care facility may choose any of those methods according to the relevant experience, technical capacity, and validation data.

Heat and humidity is a low-cost technique that could be easily implemented in a variety of settings. This method for N95 decontamination has not been validated in an FDA-approved process. More research is still needed into its effectiveness for inactivation of SARS-CoV-2. Moreover, excessive thermal cycling may damage N95 fit and filtration.

Ultraviolet irradiation **(UV-C)**, if implemented properly using sensors to ensure adequate UV-C dose to the N95, may inactivate SARS-CoV-2. Although, no effectiveness data is currently available when this method was directly applied to SARS-CoV-2.

Both, Hydrogen Peroxide Vapor **(HPV)** and Hydrogen Peroxide Gas Plasma **(HPGP)**, machine-standard protocols, when implemented properly, and N95s are not soiled, likely inactivate SARS-CoV-2. HPV systems have recently received FDA authorization, and HPGP systems are under review by the FDA. Systems and processes are complex and dangerous and require trained personnel. HPGP and HPV have distinct decontamination durations and maximum recommended reuse cycle recommendations.

Health care facilities and other agencies dependent upon PPE should return to usual protocols once the anticipated increase in PPE supply has arrived.

In the meantime, health care facilities can also refer to the following guidance issued by DHSS regarding Crisis Capacities for PPE. While it is focused on PPE use/reuse and extended use in congregate living environments, many of the concepts apply in other environments currently dependent upon the use of PPE.

Note: The situation regarding COVID-19 is rapidly changing as is our knowledge of this new disease. This guidance is based on the best information currently available and does not constitute medical advice or advocate specific treatments or approaches. Additional information regarding Personal Protective Equipment (PPE) use can be found at CDC Strategies for PPE Optimization[a].

Personal Protective Equipment (PPE)

Limited reuse and extended use options[b] – Extended use refers to the practice of wearing the same PPE (e.g., N95) for multiple encounters with several clients without removing the respirator between client encounters. **Limited reuse** refers to the practice of using the same PPE for multiple encounters with patients but doffing after each encounter. The respirator PPE is stored between encounters to be donned prior to the next encounter with a patient. If possible, limit reuse to no more than five uses per device.

Extended use is favored because it is expected to involve less touching of the respirator and therefore less risk of contact transmission. A combination of both extended use and limited reuse, with appropriate engineering and administrative controls, may optimize PPE use during crisis capacity.

Any PPE reused must only be used by a single wearer (except properly laundered cloth isolation gowns). **No sharing.** Label containers used for storing PPE or label the PPE itself (e.g., on the straps) with the name of the wearer. Do not write on the mask of a respirator (e.g., N95), as this affects the filtering efficiency.

Users should inspect PPE prior to use and discard any that is obviously damaged, soiled or any respirator if it becomes difficult to breathe through.

When using PPE optimization strategies, training on PPE use, including proper donning and doffing procedures, must be provided to staff before they carry out client care activities.[c]

Contamination Control

Although extended use and limited reuse of respirators have the benefit of conserving supplies of disposable N95 respirators, a significant risk is of contact transmission from touching the surface of the contaminated respirator. One study found that nurses averaged 25 touches per shift to their face, eyes, or N95 respirator during extended use.[d] Contact transmission occurs through direct contact with others as well as through indirect contact by touching and contaminating surfaces that are then touched by other people.

Donning (putting on) and doffing (taking off) of any type of PPE must be done in a careful and deliberate manner, taking steps to ensure the user does not touch the outer surface of the PPE during care, removal, or replacement.[c] This is especially important when donning used PPE. Since it is already contaminated, great care must be taken not to disperse the contaminants into the air or contaminate clean PPE when donning and doffing.

FACEMASK CRISIS CAPACITY STRATEGIES[e]

- Use facemasks beyond the manufacturer-designated expiration dates during patient/client care activities.
- Implement extended use and/or limited reuse practices with good contamination control.
  - Facemask removal and replacement must be done in a careful and deliberate manner taking steps to ensure the user does not touch the outer surface of the mask during care, removal, or replacement.
  - Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the facemask.
  - Avoid touching the inside of the facemask.
  - For reuse, facemasks should be carefully folded so the outer surface is held inward against itself to reduce contact with the outer surface during storage.
  - Store the mask in a clean, sealable paper bag or breathable container.
  - May also store mask in a rigid container with the lid off to allow mask to dry out.
  - Label the strap of the facemask or the container or bag with the wearer's name. Do not write on the facemask material as it will affect its permeability.
  - Discard facemask if it becomes soiled, damaged or difficult to breathe through.
  - Facemasks that fasten via ties behind the head may not be able to be undone without tearing or breaking the ties and should be considered for extended use rather than reuse.
  - Facemasks with ear loops may be more suitable for reuse.

- If no facemasks are available, the following strategies may be considered as a last resort. Please note that these are not considered PPE.
  - A homemade, double-layer cotton mask can be used if no other mask options are available.
  - Scarves and bandanas can also be used.
  - Any homemade mask should be laundered daily using routine laundry procedures.

RESPIRATOR CRISIS CAPACITY STRATEGIES[f]

- Staff wearing a tight fitting respirator must not have facial hair that would impede the seal.[g]
- Prioritize use of respirators by activity type.
  - Staff conducting activities that may generate a cough, sneeze, or gag reflex should be prioritized to wear an N95 respirator.
  - Staff giving intimate care to a patient/client.
  - Staff with higher risk of contracting severe infection from COVID-19.
  - Staff in the same room as a suspected or known COVID-19 client for a prolonged period of time.
- Use respirators beyond shelf-life[h] dated. NIOSH has tested several brand of N95 respirators and approved them for use beyond their shelf life. However, any N95 can be used beyond shelf life

after visual inspection. Make sure any elastic parts are still supple and not dried out, make sure the mask material is clean and free of defects such as tears or thin spots, and make sure the seal (edges) of the respirator is intact so it fits tightly to the face.

- Use respirators approved under standards used in other countries[i] that are similar to NIOSH but that may not necessarily be NIOSH-approved.
- Implement extended use and/or limited reuse practices with good contamination control.
  - Respirator removal and replacement must be done in a careful and deliberate manner taking steps to ensure the user does not touch the outer surface of the mask during care, removal, or replacement.
  - Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator.
  - Avoid touching the inside of the respirator.
  - Store the respirator in a clean, sealable paper bag or breathable container.
  - May also store the respirator in a rigid container with the lid off to allow it to dry out.
  - Label the strap of the respirator or the container or bag with the wearer's name. Do not write on the respirator material as it will affect its permeability.
  - Perform a visual inspection for fit and function. Discard respirator if it becomes soiled, damaged or difficult to breathe through.
  - Use a pair of clean gloves when donning a used respirator and performing a user seal check. Doff and replace gloves.
  - Perform a user seal check immediately after donning a respirator. Adjust as necessary. If you still cannot achieve a seal, do not go into the contaminated atmosphere.
- If a strap breaks during donning, attempt to tie it instead and use respirator if it still fits properly and isn't uncomfortable.
- If adequate supply exists, consider this alternative reuse method to reduce contamination:
  - Take four N95 masks, and number them (#1-4).
  - On day 1, use mask #1, then let it dry it out for 3-4 days.
  - On day 2, use mask #2, then let it dry out for 3-4 days.
  - Same for day 3, and day 4.
  - Use extreme care to avoid cross contamination or confusion of multiple used respirators.

Alternatives to typical N95s that may be considered:

- Elastomeric half-face respirators with splash goggles or full-face respirators with HEPA filters. These are more readily available than N95 respirators and the full face respirators provide eye protection.
- N99, N99, N100, R95, R99, R100, P95, P99, or P100 filtering facepiece respirators. These may be more readily available than N95 respirators, but are typically more costly.
- Powered air purifying respiratory assembly (PAPR) with HEPA filters with either a full face respirator or hood (a hood does not require fit testing).

- Controlled air purifying respirator (CAPR) unit, which also uses disposable HEPA filters, is readily available, quieter than a PAPR, and suited for hospital settings.

If there are no respirators left:

- Use facemasks if no respirators are available.
- Exclude staff at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 clients.
- Have recovered COVID-19 staff, who have some protective immunity, care for clients with known or suspected COVID-19.
- Use masks not evaluated or approved by NIOSH or homemade masks as a last resort. There is no guarantee of protection with homemade masks, but they may help against large droplets from coughs and sneezes. Homemade masks are not considered PPE.

<u>Important Note about Respiratory Protection:</u>

Respirators must be used within the context of a complete respiratory protection program that includes medical clearance, fit testing, and training. Consult with infection control, industrial hygiene, or a public health agency for more information.

If staff are using respirators, ensure they are fit tested in the type of respirator they are using and ensure they are taught the proper way to don, doff, and conduct user seal checks each time they don the respirator to ensure the proper fit.

User seal checks: https://www.youtube.com/watch?v=pGXiUyAoEd8

For a sample written respiratory protection program go to OSHA's Small Entity Compliance Guide starting on page 101.

Compliance guide: https://www.osha.gov/Publications/3384small-entity-for-respiratory-protection-standard-rev.pdf

EYE PROTECTION CRISIS CAPACITY STRATEGIES[j]

- Use eye protection devices beyond the manufacturer-designated shelf life.
- Prioritize eye protection for activities that involve splashes and sprays from coughs, sneezes, or gags, and cases where prolonged face-to-face or close contact with a suspected or known infection with COVID-19 must occur.
- Use safety glasses with side extensions if goggles are not available.
- Use a face shield.
- Use a full-face elastomeric respirator.
- Sanitize all protective eyewear with PPE wipes or other suitable cleaner after use.

ISOLATION GOWN CRISIS CAPACITY STRATEGIES[k]

- Use expired gowns beyond the manufacturer designated shelf life.
- Use coveralls (such as Tyvek suits) if available.
- Implement extended use and/or limited reuse practices with good contamination control as long as there are no additional co-infectious diseases (such as Clostridioides difficile) among patients.
  - Reuse cloth isolation gowns that are not visibly soiled.
  - Users must be careful and deliberate about removing the gowns to ensure they do not touch the front of the gown.
  - If the gown becomes visibly soiled, it must be discarded. (Or properly launder cloth isolation gowns)
- Prioritize the use of gowns for activities and procedures that may generate cough, sneeze, or gag reflexes or may cause the individual to vomit. Also for activities that involve high-contact where the transfer of pathogens to the hands and clothing of the staff may occur such as dressing, bathing, showering, transferring, providing hygiene, changing linens, toileting activities, device care or use, wound care.
- If no gowns are available, consider using washable or disposable lab coats, washable patient gowns, or disposable aprons.

<u>Decontamination and Sterilization</u>

Information is available from some manufacturers or third-parties showing that respirators can be successfully decontaminated without impacting performance. Even after decontamination, these respirators should be handled carefully.

- On March 28, 2020, FDA issued an Emergency Use Authorization (EUA) permitting the Battelle Decontamination System to be authorized for use in decontaminating "compatible N95 respirators." You can go to Battelle[l] to see if this may be an option for your organization.
- Another company, Medline[m], is seeking similar FDA approval for an alternative sterilization technique.
- A heat sterilization method has also been reported but some have not recommended due to the lack of information available. However, *Mask Ovens* made by Darwin Chambers in St. Louis, MO, are available sale for this specific purpose[o].
- A University of Nebraska Medical Center health security training team has a well-documented decontamination process[n] using ultraviolet light towers to irradiate high numbers of masks for reuse.[p]

List of URLs for hyperlinks/footnotes in text

a) https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

b) https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

c) https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html#risksextended

d) https://www.utmb.edu/covid-19/health-care-workers/don-and-doff-ppe

e) https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html

f) https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

g) https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards (OSHA Respiratory Protection Standard: 29 CFR 1910.134 [g][1][i][A] and [B]

h) https://www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html

i) https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html (scroll partway down the page to table)

j) https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html

k) https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/isolation-gowns.html

l) https://www.battelle.org/inb/battelle-critical-care-decontamination-system-for-covid19

m) https://newsroom.medline.com/supply-chain/medline-teams-working-to-provide-ppe-to-nations-healthcare-providers

n) https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf

o) Email sales@darwinchambers.com or call 314-534-3111

p) https://www.sages.org/n-95-re-use-instructions/

Health Guidance:

COVID-19 and Return to Work Messaging – Expanded Guidance for Critical Infrastructure Personnel Involved in the Provision of Direct Client Care

April 17, 2020

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The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

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April 17, 2020

FROM: **RANDALL W. WILLIAMS, MD, FACOG**
DIRECTOR

SUBJECT: **COVID-19 and Return to Work Messaging – Expanded Guidance for Critical Infrastructure Personnel Involved in the Provision of Direct Client Care**

Testing for COVID-19 remains available through the Missouri State Public Health Laboratory (SPHL) as well as commercial clinical laboratories. Clinicians who wish to submit specimens to the SPHL must submit a Missouri Person Under Investigation (PUI) and Case Report Form and a Virology Test Request for each approved patient. For more information and to access the forms, please visit the SPHL Novel Coronavirus webpage at https://health.mo.gov/lab/ncov.php. COVID-19 testing for asymptomatic individuals through any laboratory is not generally recommended. To request testing through the SPHL, providers should call the Department of Health and Senior Services Hotline at 877-435-8411.

Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever[1] and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Priorities for testing may include:

1. Hospitalized patients who have signs and symptoms compatible with COVID-19 in order to inform decisions related to infection control.
2. Symptomatic residents of congregate living facilities that house adults ages 65 or older and individuals with chronic medical conditions and/or an immunocompromised state that may put them at higher risk for poor outcomes (e.g., diabetes, chronic heart disease, such as heart failure, receiving immunosuppressive medications, chronic lung disease, chronic kidney disease).
3. Any persons including healthcare personnel (HCP)[2], who within 14 days of symptom onset had close contact[3] with a suspect COVID-19 patient with pending laboratory testing or laboratory-confirmed[4] COVID-19 patient.

There are epidemiologic factors that may also help guide decisions about COVID-19 testing. Documented COVID-19 infections in a jurisdiction and known community transmission may contribute to an epidemiologic risk assessment to inform testing decisions. Clinicians are strongly encouraged to test for other causes of respiratory illness (e.g., influenza).

Mildly ill patients should be encouraged to stay home and contact their healthcare provider by phone for guidance about clinical management. Patients who have severe symptoms, such as difficulty breathing, should seek care immediately. Older patients and individuals who have underlying medical conditions or are immunocompromised should contact their physician early in the course of even mild illness.

FOR PERSONS with COVID-19 UNDER HOME ISOLATION:
The decision to discontinue home isolation should be made in the context of local circumstances. Options now include both 1) a time-since-illness-onset and time-since-recovery (non-test-based) strategy, and 2) a test-based strategy.

1) <u>Time-since-illness-onset and time-since-recovery strategy (non-test-based strategy)</u> - Persons with COVID-19 who have symptoms and were directed to care for themselves at home may discontinue home isolation under the following conditions:
      a. At least 3 days (72 hours) have passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**
      b. At least 7 days have passed *since symptoms first appeared*.

   This recommendation will prevent most, but may not prevent all instances of secondary spread. The risk of transmission after recovery, is likely substantially less than that during illness.

2) <u>Test-based strategy</u> - Previous recommendations for a test-based strategy remain applicable, and this preferred strategy should be utilized for:

   <mark>State employees working in direct care facilities. The testing strategy remains at two negative tests, 24 hours apart before returning to work.</mark> A test-based strategy is contingent on the availability of ample testing supplies and laboratory capacity as well as convenient access to testing.

   Individuals with laboratory-confirmed COVID-19 who have not had any symptoms may discontinue home isolation when at least 7 days have passed since the date of their first positive COVID-19 diagnostic test and have had no subsequent illness

Return to Work Criteria for HCP with Confirmed or Suspected COVID-19
   Two recommended options are listed below for healthcare facilities that have employees returning to work after COVID-19 illness.
   1) <u>Non-test-based strategy</u>. Exclude from work until:
         a. At least 3 days (72 hours) have passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**
         b. At least 7 days have passed *since symptoms first appeared.*
   2) <u>Test-based strategy</u>. Exclude from work until:

a. Resolution of fever without the use of fever-reducing medications; **and**
b. Improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**
c. Negative results of an FDA Emergency Use Authorized molecular assay for COVID-19 from at least two consecutive nasopharyngeal swab specimens collected ≥24 hours apart (total of two negative specimens). See [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)](#).

HCP with laboratory-confirmed COVID-19 who have not had any symptoms should be excluded from work until 10 days have passed since the date of their first positive COVID-19 diagnostic test assuming they have not subsequently developed symptoms since their positive test.

If HCP were never tested for COVID-19 but have an alternative diagnosis (e.g., tested positive for influenza), criteria for return to work should be based on that diagnosis.

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[1] Fever may be subjective or confirmed.

[2] For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Because of their often extensive and close contact with vulnerable patients in healthcare settings, even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed healthcare personnel. Additional information is available in CDC's [Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19)](#).

[3] Close contact is defined as—
a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period of time; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case
– or –
b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on)
If such contact occurs while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection), criteria for PUI consideration are met.

Additional information is available in CDC's updated [Interim Infection Prevention and Control Recommendations for Patients with Confirmed COVID-19 or Persons Under Investigation for COVID-19 in Healthcare Settings](#).

Data to inform the definition of close contact are limited. Considerations when assessing close contact include the duration of exposure (e.g., longer exposure time likely increases exposure risk) and the clinical symptoms of the person with COVID-19 (e.g., coughing likely increases exposure risk as does exposure to a severely ill patient). Special consideration should be given to healthcare personnel exposed in healthcare settings as described in CDC's [Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with COVID-19](#).

[4] Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.